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07/200,754	05/31/88	KENSIL	0614.064004

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MAR 1 1990
RECEIVED & ACKNOWLEDGED

EXAMINER	
CARSON, N	
ART UNIT	PAPER NUMBER
183	

DATE MAILED: 02/26/90

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

11-22-89

☒ This application has been examined ☒ Responsive to communication filed on 12-1-89 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire THREE month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 29-39 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 29-39 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.

8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).

10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.

12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

SN 200754

DOCKETED
Reminder Apr 26, 1990
Final Response May 26, 1990
Stat Bar Aug 26, 1990

PTOL-326 (Rev. 7-82) EXAMINER'S ACTION

The drawings are objected to because the paper is smudged, proper margins are required, and full tone photographs on photographic paper are required for Figures 5A and 5B. Correction is required.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

In view of the papers filed November 22, 1989, it has been found that the inventive entity of the claims that are currently pending in this application is Charlotte A. Kensil and Dante J. Marciani and accordingly, this application has been corrected in compliance with 37 CFR 1.48(b). The inventorship of this application has been changed by deleting the names of Gerald A. Beltz and Chung-Ho Hung, who are not the inventors of the invention being claimed.

Claims 29-39 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29-30 and 33 are considered indefinite as to what Applicants intend to claim thereby. The claim language reads on a predominant peak on a chromatogram, *i.e.* part of a graph. It is the claim language which must particularly point out and distinctly claim the subject matter which Applicants regard as the invention. If Applicants intend to claim the substantially pure saponins, as set forth in the claims, which saponins are purified from crude Quillaja saponaria extract by a particular process, and which saponins have the certain specific characteristics as set forth in the claims, such should be affirmatively claimed. Similarly, claims 29-39 are considered indefinite as to the components intended to be encompassed by the recitation "substantially pure saponin", since the claim language does not particularly point out the subject matter intended thereby.

Claim 37 is considered indefinite in reciting "wherein said amount of said substantially pure saponin is present in an amount", as such

language is redundant and confusing. Applicants should consider deleting "present in an amount" to eliminate confusion.

The phrase "a mammalian animal" in claim 38 is confusing since such appears to exclude humans. It is unclear whether Applicants intend such.

Claim 39 is considered indefinite in reciting "wherein said saponin is a mixture of two or more of the saponins". How is a "substantially pure saponin" a "mixture of two or more of the saponins"? The recitation of claim 39 does not appear to be further limiting to the subject matter of claim 37.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> "A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 29-35 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Higuchi et al (Phytochemistry 26:229-235).

Higuchi et al discloses several substantially pure saponins isolated from a crude Quillaja saponaria extract, which saponins appear to be the same as those set forth in the instant claims. The carbohydrate components of the Higuchi et al saponins, as set forth on page 230, column 1, are the same as those set forth in the instant claims. Although the reference disclosure does not address each of the characteristics recited in the instant claims, such does not negate the teaching of the reference, as a whole, which clearly discloses substantially pure saponins which appear to be the same as those of the instant claims.

No claim is allowed.

Applicant's arguments filed November 22, 1989, together with the Declaration under 37 C.F.R. 1.132 filed December 1, 1989 have been fully considered but they are not deemed to be persuasive.

Applicant's contentions are not deemed convincing insofar as the above rejections relate to the claims. As stated above, the substantially pure saponins, as claimed, do not appear to distinguish over the substantially pure saponins of the prior art. Applicants argue that the Higuchi et al reference does not teach the isolation of compounds comprising purer and less toxic saponins. Such is not convincing since

Higuchi et al does indeed teach the isolation of saponins. While Higuchi et al may not be directed to the determination of toxicity for the saponins disclosed, the disclosure of Higuchi et al does encompass isolated saponins which appear to be the same as those of the instant claims. The Patent Office has no facilities for testing or comparing the properties of prior art compounds with those of Applicants. In the absence of evidence to the contrary, the saponins of the prior art, which otherwise appear to be the same as those claimed by Applicants, would inherently exhibit lower toxicity than crude Quillaja saponaria extract. Moreover, Higuchi et al is concerned with isolating "the physiologically active triterpenoid compounds", which indicates that the isolated compounds are those believed to retain the activity reported for saponin mixtures, *i.e.* strong adjuvant activity.

Applicant's Declaration has been fully considered but is not deemed convincing insofar as the above rejection relates to the claims. No comparison of the isolated saponin components taught by Higuchi et al with Applicant's substantially pure saponin components is found. Applicant states that Higuchi et al makes no reference to the possibility that any particular saponin would have adjuvant activity, including those isolated therein. Such is not convincing since Higuchi et al, as stated above, is concerned with isolating the physiologically active triterpenoid compounds.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE

THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

An inquiry concerning this communication should be directed to Nancy Carson at telephone number (703) ~~557-0664~~ 308-0196.

NSC

N.S.Carson

2/21/90

Ronald W. Griffin

RONALD W. GRIFFIN
PRIMARY EXAMINER
ART UNIT 183